K 111555

5.

510(k) Summary

JUL 25 2011

Submitter's Information:	R&D Medical Products, Inc. 20492 Crescent Bay Drive, Building 106 Lake Forest, CA 92630
Contact Person:	James Perrault Phone: (949) 472-9346 x202 Fax: (949) 472-9347
Date Prepared:	May 31, 2011
Proprietary Name:	Circumaural Adhesive Replacement
Common Name:	Disposable Ear Phone Hydrogel Adhesive
Classification Name:	Stimulator, Auditory Evoked Response [an Accessory Component modification to]
Regulation:	Evoked Response Auditory Stimulator, 21 C.F.R. §882.1900
Regulatory Class:	Class II
Product Code:	GWJ
Predicate Devices:	ALGO-3 Newborn Hearing Screener and Accessories (specifically the Flexicoupler Disposable Earphone accessory), K013137
Description of Device:	Circumaural Adhesive Replacement is acrylic hydrogel adhesive rings supplied on a release card in a packages of ten. After the original adhesive is removed from the disposable ear couplers, the top liner covers are removed to apply the adhesive rings to the earphones thereby making them reusable and reducing medical test costs. The then reusable ear couplers with the disposable adhesive rings are placed around the infant ears for the duration of the test. The Circumaural Adhesive Replacement is then removed and discarded. After an alcohol wipe of the same earphones, another Circumaural Adhesive Replacement is applied for the next patient test.
Indications for Use:	The Circumaural Adhesive Replacement is used to make earphones reusable for newborn hearing screening tests. It is a

	single use disposable to seal the earphones in place during the screening process. This skin adhesive is intended for use on the circumaural area of babies between the ages of 34 weeks (gestational age) and 6 months. Sites appropriate for this screening test may include the well-baby nusery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.
Technological Comparison:	The Circumaural Adhesive Replacement on the Natus Flexicouplers has technological characteristics that are substantially equivalent to those of the predicate device as determined by testing and common materials.
Basis for Equivalence:	R&D Medical Products, Inc. has manufactured predicate device accessories for Natus and now seeks to make the adhesive replacement component under private label for distribution. See Substantial Equivalence Table on following page.
-Performance testing:	Biocompatibility testing was performed and the device passed the required skin sensitivity testing criteria. According to the performance data, the Circumaural Adhesive Replacement met specifications as established in ISO 10993-1 for skin contact. The tests included cytotoxicity, sensitization and primary skin irritation tests. The predicate device uses the same materials and meet the same ISO 10993 specifications. Bench testing demonstrated that the adhesive characteristics of the Circumaural Adhesive Replacement are substantially equivalent to those of the predicate device.
-Labeling:	The labeling of the Circumaural Replacement Adhesive is substantially equivalent to that of the predicate device after the replacement is done.
Conclusions from Testing:	In all material respects, the Circumaural Adhesive Replacement on the Natus Flexicoupler is substantially equivalent to the predicate device. Both use acrylic hydrogel adhesives. Test results support the conclusion that the adhesive performance is substantially equivalent to the predicate devices, and there are no differences in construction and materials between the devices to pose new questions of safety or effectiveness.

Substantial Equivalence Table

Parameter	**Predicate** **K013137** **Natus Medical Inc.** **Flexicoupler**	**Applicant** **Kxxxxxx** **R&D Medical Products, Inc.** **Circumaural Adhesive Replacement**
Contract Manufacturer	R&D Medical Products, Inc (until 2005)	R&D Medical Products, Inc
Skin Contact Material	Acrylic Hydrogel (original)	Acrylic Hydrogel (replacement)
Ear Phone	Flexicoupler Rubber Molded Part	Flexicoupler Rubber Molded Part
Contact Area	3.2 square inches	3.2 square inches
Hydrogel Attachment to Coupler	100%	100%
Acoustic Seal	100%	100%
Adhesive Residue	0%	0%
Pain Upon Removal	None	None
Biocompatibility	Passed ISO 10993	Passed ISO 10993
Indications for Use	Newborn Hearing Screening	Newborn Hearing Screening
Shelf Life	Two Years	Two Years
Prescription/OTC Status	Prescription	Prescription

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

R & D Medical Products, Inc.
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JUL 25 2011

Re: K111555
Trade/Device Name: Circumaural Adhesive Replacement
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoke Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: May 31, 2011
Received: June 03, 2011

Dear Mr. Perrault:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111555

Indications for Use

510(k) Number (if known): __K111555__

Device Name: ___ Circumaural Adhesive Replacement ____

Indications for Use:

The Circumaural Adhesive Replacement is used to make earphones reusable for newborn hearing screening tests. It is a single use disposable to seal the earphones in place during the screening process. This skin adhesive is intended for use on the circumaural area of babies between the ages of 34 weeks (gestational age) and 6 months. Sites appropriate for this screening test may include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

Prescription Use ___**X**____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111555